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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/561,571	12/21/2005	Meng Hsin Chen	21406YP	5907				
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 12/02/2009		<table border="1"><tr><td>EXAMINER</td></tr><tr><td>BALASUBRAMANIAN, VENKATARAMAN</td></tr></table>		EXAMINER	BALASUBRAMANIAN, VENKATARAMAN		
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			<table border="1"><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td colspan="2">1624</td></tr></table>	ART UNIT	PAPER NUMBER	1624		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/561,571

**Applicant(s)**

CHEN ET AL.

**Examiner**/Venkataraman  
Balasubramanian/**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 is/are allowed.
- 6) ☐ Claim(s) 16-18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 09/08/2008
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' response, which included amendment to claim 16 and 19, filed on 7/30/2009, is made of record. Claims 16-24 are pending. In view of applicants' response the 112 second paragraph rejection and first paragraph rejection made in the previous office action have been obviated. However, the following new grounds of rejections are applied to currently pending claims.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-18 and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by M. Mjalli et al., US 2003/0032663.

Mjalli teaches several benzimidazole compound of formula I useful for treating diabetic late complications such as retinopathy, which include instant compounds. See page 2, formula I and the definition of variable groups. Note when instant W is second choice and Y is first choice, the compounds taught by Mjalli include instant compounds. See pages 2-5 for details of the invention, pages 5-9 for Table 1, examples of compounds made, pages 11-13 for process of making and pages 14-19, for Examples 1-16.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Nikolaides et al., WO 01/58878 (equivalent to US 2003/0216582 which is used for the subject matter of invention. An Abstract of WO 01/58878 provided.).

Nikolaides teaches several 2-carboxamide-benzimidazole compound of formula I useful for treating ischemia, which include instant compounds. See page 1, formula I and the definition of variable groups. Note when R<sup>1</sup> is alkyl, the compounds taught by Nikolaides include instant compounds. See pages 1-9 for details of the invention, compounds made and process of making.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al., US 6,204,264.

Kobayashi teaches several 2-carboxamide-benzimidazole compound of formula I useful for treating hair loss, which include instant compounds. See column 2, formula I and the definition of variable groups. Especially note with the given definition of A and B, the compounds taught by Kobayashi include instant compounds. See pages 1-12 for details of the invention and process of making. See column 13-48 for examples 1-43 for compounds made.

Claims 16-18 and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Franz et al., US 5,294,631.

Franz teaches several benzimidazole compounds of formula I useful for glaucoma and hypertension, which include instant compounds. See column 4, formula I and the definition of variable groups. Especially, note with the given definition of R<sup>2</sup> and R<sup>1</sup>, the compounds taught by Franz include instant compounds. See pages 4-14 for

details of the invention, preferred species and process of making. See column 17-30 for examples 1-24 for compounds made.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Spang et al., US 5,008,397.

Spang teaches several N-substitutedbenzimidazole2-carboxanilide compound of formula I useful as light stabilizer which includes instant compounds. See column 1, formula I and the definition of variable groups. Note when  $n=1$  and  $R_5$  is alkyl, cycloalkyl, hydroxyalkyl group, with the given definition of other variable groups, the compounds taught by Spang include instant compounds. See column 1-8 for details of the invention and column 8-21 for various compounds made.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Spang et al., US 4,985,566.

Spang teaches several N-substituted-benzimidazole2-carboxanilide compound of formula I useful as light stabilizer which includes instant compounds. See column 1, formula I and the definition of variable groups. Note when  $n=1$  and  $R_5$  is alkyl, cycloalkyl, hydroxyalkyl group, with the given definition of other variable groups, the compounds taught by Spang include instant compounds. See column 1-10 for details of the invention and column 10-25 for examples 1-64 of compounds made.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al., 4,925,853.

Smith teaches several benzimidazole compound of formula I useful for treating allergy and gastrointestinal disorder, which include instant compounds. See column 1,

formula I and the definition of variable groups. Note when R<sup>3</sup> is lower alkyl or COR<sup>8</sup>, with the given definition of other variable groups, the compounds taught by Smith include instant compounds. See column 1-4 for details of the invention and column 7-18 for process of making these compounds. See column 18-29 for Examples 1-38. Especially see Examples 34 and 38.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al., 4,142,886.

Hunter teaches several benzimidazole compound of formula I useful for treating allergy and gastrointestinal disorder, which include instant compounds. See column 1, formula I and the definition of variable groups. Note when R<sub>1</sub> and R<sub>2</sub> are lower alkyl of 1-3 carbons, with the given definition of other variable groups, the compounds taught by Hunter include instant compounds. See column 1-2 for details of the invention and for process of making these compounds. See column 3-4 for Examples I-XVII.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaloplssis et al., US 3,856,810.

Kaloplssis teaches several 4-hydroxy-7-methyl benzimidazole compound of formula I useful for hair dyeing, which includes instant compounds. See column 1, formula I and the definition of variable groups. Note when R<sub>5</sub> is methyl and R<sub>4</sub> is lower alkyl of 1-4 carbons, with the given definition of other variable groups, the compounds taught by Kaloplssis include instant compounds. See column 1-2 for details of the invention and for process of making these compounds. See column 3-5 for Examples 1-6.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Janiak et al., US 3,821,393.

Janiak teaches several benzimidazole compound of formula I useful as pesticides which includes instant compounds. See column 1, formula I and the definition of variable groups. Note when  $R_4$  is aliphatic or cycloaliphatic group, with the given definition of X,  $R_5$  and other variable groups, the compounds taught by Janiak include instant compounds. See column 1-2 for details of the invention and column 2-7 for various compounds made.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shen et al. US 3,590,047.

Shen teaches several benzimidazole compound of formula shown in column 1 useful for treating arthritis, which includes instant compounds. See column 1, formula I and the definition of variable groups. Note with the given definition of A, M,  $R_2$  and  $R_3$  groups, the compounds taught by Shen include instant compounds. See column 1-7 for details of the invention and for process of making these compounds. See column 7-12 for Examples 1-12.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shen et al. US 3,586,694.

Shen teaches several benzimidazole compound of formula shown in column 1 useful for treating arthritis, which includes instant compounds. See column 1, formula I and the definition of variable groups. Note with the given definition of A, M,  $R_2$  and  $R_3$  groups, the compounds taught by Shen include instant compounds. See column 1-10

for details of the invention and for process of making these compounds. See column 10-19 for Examples 1-18.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldsmith et al., US 3,325,271

Goldsmith teaches several benzimidazole compound of formula I useful as herbicides which includes instant compounds. See column 1, formula I and the definition of variable groups. Note when  $R_1$  is alkyl and  $R_2$  is alkyl or alkoxyalkyl, with the given definition of other variable groups, the compounds taught by Goldsmith include instant compounds. See column 1-2 for details of the invention and column 2-9 for Examples I-XXIV.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Richter et al., US 3,265,691

Richter teaches several 1-benzyl-benzimidazole compound of formula I useful as herbicides which includes instant compounds. See column 1, formula I and the definition of variable groups. Note when  $R_3$  is alkyl, haloalkyl, alkoxyalkyl and aminoalkyl, with the given definition of other variable groups, the compounds taught by Richter include instant compounds. See column 1-6 for details of the invention, preferred species and process of making them. See column 9-22 for Examples of compounds made.

Claims 16-18 and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaiser et al., US 4,728,741.



Kaiser teaches several 1-substituted-2-mercaptobenzimidazole compound of formula I useful as vasodilator which includes instant compounds. See column 2, formula I and the definition of variable groups. Note when Y =SR, with the given definition of other variable groups, the compounds taught by Kaiser include instant compounds. See column 1-9 for details of the invention, preferred species and process of making them. See column 11-20 for Examples 1-65 of compounds made.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Briving et al., EP 0266326

Briving teaches several benzimidazole compound of formula I useful for treating ulcer which includes instant compounds. See page 2, formula I and the definition of variable groups. Note when R<sub>3</sub> is alkyl, phenylalkyl or cycloalkyl-alkyl with the given definition of other variable groups, the compounds taught by Briving include instant compounds. See pages 2-11 for details of the invention, Table 1 for species and process of making them. See pages 11-18 for Examples of compounds made.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over M. Mjalli et al., US 2003/0032663.

Mjalli teaches several benzimidazole compound of formula I useful for treating diabetic late complications such as retinopathy, which include instant compounds. See page 2, formula I and the definition of variable groups. Note when instant W is second choice and Y is first choice, the compounds taught by Mjalli include instant compounds. See pages 2-5 for details of the invention, pages 5-9 for Table 1, examples of compounds made, pages 11-13 for process of making and pages 14-19, for Examples 1-16.

Mjalli differs in not exemplifying all compounds of formula I generically claimed but exemplifies only selected number of compounds as seen in Table 1 and examples 1-16. However, Mjalli teaches equivalency of those compounds exemplified with those generically claimed. Hence, it would be obvious to one trained in the art to make the compound of formula I including instant compounds an expect theme to have the use taught therein.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., 4,925,853.

Smith teaches several benzimidazole compound of formula I useful for treating allergy and gastrointestinal disorder, which include instant compounds. See column 1,

formula I and the definition of variable groups. Note when  $R^3$  is lower alkyl or  $COR^8$ , with the given definition of other variable groups, the compounds taught by Smith include instant compounds. See column 1-4 for details of the invention and column 7-18 for process of making these compounds. See column 18-29 for Examples 1-38. Especially see Examples 34 and 38.

Smith differs in not exemplifying all compounds of formula I generically claimed but exemplifies only selected number of compounds as seen examples 1-38. However, Smith teaches equivalency of those compounds exemplified with those generically claimed. Hence, it would be obvious to one trained in the art to make the compound of formula I including instant compounds an expect theme to have the use taught therein.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briving et al., EP 0266326

Briving teaches several benzimidazole compound of formula I useful for treating ulcer which includes instant compounds. See page 2, formula I and the definition of variable groups. Note when  $R_3$  is alkyl, phenylalkyl or cycloalkyl-alkyl with the given definition of other variable groups, the compounds taught by Briving include instant compounds. See pages 2-11 for details of the invention, Table 1 for species and process of making them. See pages 11-18 for Examples of compounds made.

Briving differs in not exemplifying all compounds of formula I generically claimed but exemplifies only selected number of compounds as seen examples 1-22. However, Briving teaches equivalency of those compounds exemplified with those generically

claimed. Hence, it would be obvious to one trained in the art to make the compound of formula I including instant compounds an expect theme to have the use taught therein.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nikolaides et al., WO 01/58878 (equivalent to US 2003/0216582 which is used for the subject matter of invention. An Abstract of WO 01/58878 provided.).

Nikolaides teaches several 2-carboxamide-benzimidazole compound of formula I useful for treating ischemia, which include instant compounds. See page 1, formula I and the definition of variable groups. Note when  $R^1$  is alkyl, the compounds taught by Nikolaides include instant compounds. See pages 1-9 for details of the invention, compounds made and process of making.

Nikolaides differs in not exemplifying all compounds of formula I generically claimed but exemplifies only selected number of compounds as seen examples. However, Nikolaides teaches equivalency of those compounds exemplified with those generically claimed. Hence, it would be obvious to one trained in the art to make the compound of formula I including instant compounds an expect theme to have the use taught therein.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al., US 6,204,264.

Kobayashi teaches several 2-carboxamide-benzimidazole compound of formula I useful for treating hair loss, which include instant compounds. See column 2, formula I and the definition of variable groups. Especially note with the given definition of A and B

, the compounds taught by Kobayashi include instant compounds. See pages 1-12 for details of the invention and process of making. See column 13-48 for examples 1-43 for compounds made.

Kobayashi differs in not exemplifying all compounds of formula I generically claimed but exemplifies only selected number of compounds as seen pages 13-48 & examples 1-43. However, Kobayashi teaches equivalency of those compounds exemplified with those generically claimed. Hence, it would be obvious to one trained in the art to make the compound of formula I including instant compounds an expect theme to have the use taught therein.

Claims 16-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vazquez US 5,216,003.

Vazquez teaches benzimidazole compound of formula I useful for treating ischemia, which generically include instant compounds. See column 3, formula I and the definition of variable groups. Especially note when V is alkyl, cycloalkylalkyl, hydroxyalkyl, alkoxyalkyl or araalkyl, with the given definition of A, Y, X and B, the compounds taught by Vazquez include instant compounds. See column 3-21 and column 25-34 for details of the invention, specific compounds made and process of making.

Vasquez differs in not exemplifying all compounds of formula I wherein V is alkyl, cycloalkylalkyl, hydroxyalkyl, alkoxyalkyl or araalkyl, generically claimed but exemplifies number of compounds wherein V is H, as seen column 3-21. However, Vasquez teaches equivalency of those compounds exemplified with those generically

claimed. Hence, it would be obvious to one trained in the art to make the compound of formula I including instant compounds an expect theme to have the use taught therein.

Furthermore, while compounds exemplified by Vazquez do not anticipate the scope of instant claims, they are very closely related having NH in the reference versus NCH<sub>3</sub> in the instant claims. However, compounds that differ only in having H vs Me on nitrogen are not deemed patentably distinct absent evidence of superior or unexpected properties. See for compounds that differ only as H vs Me on nitrogen, Ex parte Weston 121 USPQ 428; In re Doebel 174 USPQ 156.

Thus, one skilled in the art at the time of the invention would have been motivated to make compounds that have methyl on the nitrogen and expect the these compounds to possess the utility in the instant case in view of the close structural similarity outlined above.

#### ***Allowable Subject Matter***

Claim 19 is allowed.

#### **Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any

inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/  
Primary Examiner, Art Unit 1624